



The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte DIANA NGUYEN-THIEN-NHON, MYRON HOWANEC JR.,
RALPH KAFESJIAN, DELOS M. COSGROVE, ROBERT STOBIE and HUNG LY LAM

Appeal No. 2005-0957
Application No. 09/745,386

ON BRIEF

Before FRANKFORT, NASE, and BAHR, Administrative Patent Judges.
FRANKFORT, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's final rejection of claims 1-4, 24 and 25. Claims 5-7 and 26, the only other claims remaining have been withdrawn from further prosecution as being drawn to a non-elected species. Claims 8-23 were cancelled by an amendment filed April 12, 2000.

THE INVENTION

The appellants' invention relates to an improved holder for implanting a tissue-type prosthetic mitral heart valve that helps prevent suture looping during the valve implantation procedure. The holder includes two relatively movable plate-like portions (40, 44), one of which attaches to a sewing ring on the inflow end of the valve. The other plate-like portion attaches via flexible lengths of material (e.g., sutures) to circumferentially spaced valve commissure posts (26) located at the outflow end of the valve. Separation of the plate-like portions places the flexible lengths of material (60) in tension and radially constricts the flexible commissure posts for facilitating implanting the valve outflow end first. The flexible lengths of material (60) extend between the valve commissure posts and each flexible length of material crosses over the adjacent flexible length of material just radially inward from the commissure post tips to create a barrier to suture looping which guides loose sutures over each post tip (62).

Representative claim 1 reads as follows:

A holder for a tissue-type prosthetic heart valve attachable to a surgical delivery handle, the heart valve having an inflow end and an outflow end and a flow axis therebetween, the valve including an annular suture ring at the inflow end and a plurality of generally axially extending commissure posts circumferentially-spaced around the outflow end that support occluding tissue surfaces of the valve, the holder comprising:

a plurality of lengths of flexible material extending in a taut fashion across the outflow end of the valve to prevent suture looping, each length of material having a first segment extending directly between adjacent commissure posts and crossing over (i.e., intersecting) each adjacent length of material just radially inward from the commissure post therebetween.

Appeal No. 2005-0957
Application No. 09/745,386

THE PRIOR ART

The prior art reference of record relied upon by the examiner in rejecting the appealed claims is:

Carpentier et al. (Carpentier)	4,865,000	Sep. 12, 1989
--------------------------------	-----------	---------------

THE REJECTION

Claims 1-4, 24 and 25 stand rejected under 35 U.S.C. § 103 (a) as being unpatentable over Carpentier.

Rather than reiterate the conflicting viewpoints advanced by appellants and the examiner regarding the above noted rejection, we refer to the examiner's answer (mailed May 16, 2003) and appellants' revised brief (filed February 21, 2003) and reply brief (filed July 15, 2003) for a full exposition thereof.

OPINION

Having carefully reviewed the obviousness issue raised in this appeal in light of the record before us, we make the determination that follows.

Regarding the examiner's rejection of claim 1, we note that the examiner correctly states that Carpentier discloses all the limitations of claim 1 except for each

Appeal No. 2005-0957
Application No. 09/745,386

length of flexible material crossing over (i.e., intersecting) each adjacent length of flexible material just radially inward from the commissure post therebetween. To address this difference, the examiner asserts that it would have been an obvious matter of design choice to cross over the flexible lengths of material (19) of Carpentier just radially inward from the commissure post therebetween because the applicants have not disclosed that this provides an advantage, is used for a particular purpose, or solves a stated problem not mentioned in the Carpentier reference. The examiner also asserts that one of ordinary skill in the art would have expected the invention to perform equally well with the flexible lengths of material (sutures) not crossing over each other. See pages 3-4 of the examiner's answer.

Suffice to say that the examiner has not provided an evidentiary basis for the proposed modification of the arrangement of the flexible lengths of material (sutures) of the Carpentier valve holder necessary to arrive at the valve holder claimed by appellants, and that the Carpentier patent provides none. Instead the examiner has merely proffered conclusory statements that it would have been an obvious matter of design choice to a person of ordinary skill in the art, and that one of ordinary skill in the art would have expected the invention to perform equally well without the sutures crossing over. The examiner is reminded that a rejection based on § 103 must rest on a

Appeal No. 2005-0957
Application No. 09/745,386

factual basis, with the facts being interpreted without hindsight reconstruction of the invention from the prior art. In making this evaluation, the examiner has the initial duty of supplying the factual basis for the rejection he advances. He may not, because he doubts that the invention is patentable, resort to speculation, unfounded assumptions or hindsight reconstruction to supply deficiencies in the factual basis. See In re Warner, 379 F.2d 1011, 154 USPQ 173 (CCPA, 1967). Since the examiner has failed to make out a prima facie case of obviousness, we will not sustain the rejection of claim 1 under 35 U.S.C. § 103 as being unpatentable over Carpentier.

Concerning dependent claims 2-4, 24 and 25, we note that appellants have indicated on page 3 of their brief that these claims are grouped to stand or fall with claim 1. Thus, given our disposition of claim 1 above, it follows that the rejection of claims 2-4, 24 and 25 under 35 U.S.C. § 103 as being unpatentable over Carpentier is also reversed.

Furthermore, the examiner's statement that the appellants have not disclosed that the crossing over of the sutures (flexible lengths of material) provides an advantage or is used for a particular purpose is inaccurate. Appellants' specification at page 10, lines 12-15 expressly notes that the intersection of the sutures (flexible lengths of material) defines a plane or slide closely adjacent to each commissure post tip that helps prevent suture looping because a barrier is provided that guides loose sutures

Appeal No. 2005-0957
Application No. 09/745,386

over each commissure post tip. Appellants have pointed out these advantages in their revised appeal brief at page 4 and in their reply brief at page 3. The examiner has failed to specifically address these advantages despite their explicit identification by appellants.

As for the examiner's assertion that one of ordinary skill in the art would have expected the invention to perform equally well with the flexible lengths of material (sutures) not crossing over each other, the examiner has provided no explanation of why this would be the case and no cogent rationale or reason for dismissing appellants' invention out of hand.

CONCLUSION

In summary:

The rejection of claims 1-4, 24 and 25 under 35 U.S.C. § 103 (a) as being unpatentable over Carpentier is reversed.

Appeal No. 2005-0957
Application No. 09/745,386

The decision of the examiner is reversed.

REVERSED

CHARLES E. FRANKFORT
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

JENNIFER D. BAHR
Administrative Patent Judge

)
)
)
)
)
) BOARD OF PATENT
) APPEALS
) AND
) INTERFERENCES
)
)
)
)
)

CEF/lbg

Appeal No. 2005-0957
Application No. 09/745,386

Edwards Lifesciences Corporation
One Edwards Way
Irvine, CA 92614